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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/084,578	02/27/2002	James L. DiGuiseppe	9250-29	6023
7590 12/24/2009				
bioMerieux, Inc. Patent Department 100 Rodolphe Street Durham, NC 27712			EXAMINER BEISNER, WILLIAM H	
			ART UNIT 1797	PAPER NUMBER
			MAIL DATE 12/24/2009	DELIVERY MODE PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/084,578

Applicant(s)

DIGUISEPPI ET AL.

Examiner

WILLIAM H. BEISNER

Art Unit

1797

Period for Reply -- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 08 September 2009.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 41-67 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 41-45, 48-56 and 66 is/are allowed.
- 6) ☒ Claim(s) 46, 47, 57-65 and 67 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SF/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(c), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(c) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 9/8/2009 has been entered.

Claim Rejections - 35 USC § 112

2. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

3. Claims 46, 47 and 57-65 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In claims 46, 47 and 57-65, line 1, "The device" lacks antecedent basis. Note claim 45 from which these claims depend recites a product rather than a device. Clarification and/or correction is requested.

Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are

such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

5. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

6. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

7. Claim 67 is rejected under 35 U.S.C. 103(a) as being unpatentable over Gordon (US 4,215,198) in view of Calandra et al.(US 5,094,955) alone or alternatively further in view of Friedman et al.(US 4,829,005).

The reference of Gordon discloses a filtration and detection device that includes a container (11, 111) defining a chamber and having an inlet (43, 143) and an outlet (31, 131) in fluid communication with the chamber. The device includes a filter (23, 123) for filtering fluids and is mounted between the inlet (43, 143) and outlet (32, 131).

While the reference of Gordon discloses adding culture medium to the filter chamber and detecting color or turbidity changes for determining the presence of microorganisms in the sample fluid (See column 1, line 65, to column 2, line 6, and column 4, lines 40-56), claim 67 differs by reciting that the device includes a sensor mounted in the chamber wherein the sensor is positioned at an opposite end of the chamber from the filter and includes a measuring apparatus operable to detect the measurable property of the sensor.

The reference of Calandra et al. discloses that it is known in the art to mount a growth detection sensor (2) within a sealed culture vessel (1). The reference discloses that using the sensor is advantageous over conventional turbidity and/or color change detections because errors resulting from the presence of interfering materials in the sample can be reduced (See column 2, lines 20-45). The reference also discloses the use of a measurement apparatus (4-8).

In view of this teaching, it would have been obvious to one of ordinary skill in the art at the time the invention was made to employ a sensor and measurement device as taught by the reference of Calandra et al. in the container of the primary reference for the known and expected result of increasing the detecting efficiency within the detection device resulting from the use of the sensor of Calandra et al.

If the vessel of Gordon is considered to not be sealed in a manner adequate to be used with the sensing device of Calandra et al., the reference of Friedman et al. is cited to evidence that it is known in the art of sterility testing to construct the filtration device or container in a gas-tight manner so as to avoid contamination (See column 2, lines 14-26; column 8, lines 9-34).

In view of this teaching, it would have been obvious to one of ordinary skill in the art at the time the invention was made to construct the filtration device of the reference of Gordon in a

gas-tight manner, if not inherent, for the known and predictable result of preventing contamination of the interior of the container and/or surrounding environment in which the container is employed.

With respect to the location of the sensor, the reference of Calandra discloses that the sensor can be positioned on the bottom of the container or in the sealing means of the container (See column 3, lines 61-68).

As a result, it would have been obvious to one of ordinary skill in the art to determine the optimum location for the sensor within the container while ensuring that the sensor is visible from outside the container. Specifically, in view of the teaching of Calandra, it would have been obvious to one of ordinary skill in the art to position the sensor on the cap (15, 115) of the device of Gordon. Note, in an already known device, the rearrangement or placement of parts that does not alter the operation of the device is not a patentable distinction (See *In re Kuhle*, 526 F.2d 553, 188 USPQ7 (CCPA 1975). The configuration resulting from the teachings of Gordon and Calandra would result in a device wherein the sensor is parallel to and against an end wall of the chamber and wherein the chamber is transparent such that the sensor can be detected through the chamber. Note the presence of culture medium within the device fails to further limit the structure of the device because it is considered material worked on (See *MPem* 2115). Additionally, statement of the orientation of the device during use fails to further distinguish the structure of the device since statements of intended use fail to further distinguish structure of the device.

Response to Arguments

8. Applicant's arguments with respect to claims 1-5, 7, 9, 11-15, 17, 18, 20, 21, 29, 35, 39 and 40 have been considered but are moot since the claims have been cancelled.

Allowable Subject Matter

9. Claims 41-45, 48-56 and 66 are allowed.
10. Claims 46, 47 and 57-65 would be allowable if rewritten to overcome the rejection(s) under 35 U.S.C. 112, 2nd paragraph, set forth in this Office action and to include all of the limitations of the base claim and any intervening claims.
11. The following is a statement of reasons for the indication of allowable subject matter:
- With respect to claims 41-44, 48-56 and 66, the prior art of record fails to teach or fairly suggest a device of the claimed structure of claim 41 including the use of a container wherein the end wall defines a continuous closed surface that is continuous with the side wall and free of openings. One of ordinary skill in the art would not have been motivated to modify the container of the closest prior art of Gordon (US 4,215,198) to have such a continuous wall construction since the device of Gordon requires that the lid or cover be removable during use and/or include a vent port.
- With respect to claims 45-47 and 57-65, the prior art of record fails to teach or fairly suggest a product of the claimed combination of elements as recited in claim 45 including a liquid culturing medium in the lower end of the chamber contacting the sensor positioned in the lower end of the chamber. One of ordinary skill in the art would not have been motivated to

modify the container of the closest prior art of Gordon (US 4,215,198) to include a culture medium in a lower chamber which contacts a sensor also provided in the lower chamber of the device.

Conclusion

12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to WILLIAM H. BEISNER whose telephone number is (571)272-1269. The examiner can normally be reached on Tues. to Fri. and alt. Mon. from 6:15am to 3:45pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael A. Marcheschi, can be reached on 571-272-1374. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

**/William H. Beisner/
Primary Examiner
Art Unit 1797**

WHB